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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,027	11/14/2003	Romano Mongiorgi	2503-1074	7509

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EXAMINER

FLOOD, MICHELE C

ART UNIT PAPER NUMBER

1654

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/712,027	MONGIORGI	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michele Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Acknowledgment is made of the receipt and entry of the amendment filed on February 28, 2005.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Response to Arguments***

##### ***Claim Rejections - 35 USC § 101***

Claim 6 as amended is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Newly applied as necessitated by amendment.

The instant claim is drawn to a product of nature, namely a plant of either *Rheum* genus or *Spinacia oleracea* L.

##### ***Claim Rejections - 35 USC § 112***

Claims 2-4 and 6-9 as amended and newly added Claim 10 remain/is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Claims 2-4 recite the limitation "the plant compounds" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 1654

Claim 6 is rendered incomplete because while the preamble of the claim is directed to a method of treating dentinal hypersensitivity in a patient no process steps for the instantly claimed method are recited therein. Thus, it is unclear as to how the claimed method of treatment is effected since Claim 6, as drafted, merely reads on a composition comprising a claim-designated active ingredient, wherein the active ingredient comprises at least one compound selected from the group consisting of *Rheum genus* and *Spinacia oleracea L.* versus the administration thereof a claim-designated active ingredient.

The metes and bounds of Claim 10 are rendered indefinite by the phrase "wherein said compounds are obtained by hydroalcoholic extraction" because it is uncertain as to whether Applicant intends to direct the subject matter of the claimed invention to a composition comprising an extract of the claim-designated plants or compounds obtained from the claim-designated plants. For example, a hydroalcoholic extraction of a plant generally results in the making of an extract versus a compound since a process of preparing a compound from plant materials generally not only involves extraction but also isolation and purification of a crude plant extract to obtain a plant compound. The lack of clarity renders the claim very ambiguous.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 USC § 102***

Claim 1 as amended is rejected under 35 U.S.C. 102(b) as being anticipated by Pan et al. (CN 1068215 C), Song (CN 1101856 A) and Gortner et al. (UU1). Newly applied as necessitated by amendment.

Applicant claims a composition comprising an effective amount of an active ingredient to treat dentinal hypersensitivity and a suitable excipient, wherein said active ingredient is selected from the group consisting of *Rheum genus* and *Spinacia oleracea* L.

Pan teaches a composition comprising an alcohol extract obtained from rhubarb roots that used for eliminating pain. It is noted that Pan does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Song teaches a composition comprising an alcohol extract obtained from rhubarb roots. Song further teaches that use of the referenced composition does not require an analgesic or anesthetic and that no hypersensitivity is experienced. It is noted that Song does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish

Art Unit: 1654

the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Gortner teaches compositions comprising the claim-designated plants and a suitable excipients. For instance, Gortner teaches a composition comprising dry spinach leaves combined with a ground dog feed diet (a suitable excipient) and rhubarb juice. Gortner further teaches administering effective amounts of either of the spinach leaf extract and animal feed or rhubarb juice to rats bearing acid eroded teeth wherein destruction of tooth occurred formed a hard deposit on the molars of the rats. See page 126, line 5 to page 127, line 4 and page 127, lines 24-26.

It is noted that Gortner does not teach that the composition(s) can be used in the manner instantly claimed, however, the intended use of the claimed composition(s) does not patentably distinguish the composition(s), *per se*, since such undisclosed use is inherent in the reference composition(s). In order to be limiting, the intended use must create a structural difference between the claimed composition(s) and the prior art composition(s). In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Further note:

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the

Art Unit: 1654

claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims and MPEP § 2141.02 with regard to inherency .

Each of the references of Pan, Song and Gortner anticipates the claimed subject matter.

**No claims are allowed.**

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1654

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**MICHELE FLOOD**  
**PRIMARY EXAMINER**

Michele Flood  
Examiner  
Art Unit 1654

MCF  
May 10, 2005